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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,809	07/21/2003	S. Ananth Karumanchi	01948/088004	6646
21559	7590	12/31/2007		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER DANG, IAN D	
			ART UNIT 1647	PAPER NUMBER
			NOTIFICATION DATE 12/31/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

### Office Action Summary

**Application No.**

10/624,809

**Applicant(s)**

KARUMANCHI ET AL.

**Examiner**

IAN DANG

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41, 42, 44-50, 54-56, 58-68 and 70-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41, 49, 54, 55, 59, 60, 67, 68, 74, 76-80, 82, 83, 85-88 and 91 is/are allowed.
- 6) ☒ Claim(s) 42, 44-48, 50, 56, 58, 61-66, 70-73, 75, 81, 84, 89, and 90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/26/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 26 October 2007 has been entered in full. Claims 1-40, 43, 51-53, 57, 69 have been cancelled and claims 42, 45, 47, 48, 49, 50, 58-62, 64, 65, 68, 70-72, and 77-78 have been amended. Claims 82-91 have been added.

Claims 41-42, 44-50, 54-56, 58-68, 70-91 are pending and under examination.

### **Rejections Withdrawn**

#### ***35 USC § 112, First Paragraph (Written Description)***

Applicant's response and arguments filed on 10/26/2007 have overcome the rejection of claims 42-50, 54-56, 58-68 and 70-81 under 35 USC 112, First paragraph (Written Description). The rejection of claims 42-50, 54-56, and 70-81 under 35 USC 112, First paragraph (Written Description) has been withdrawn.

#### ***35 USC § 112, First Paragraph (Enablement)***

Applicant's response and arguments filed on 10/26/2007 have overcome the rejection of claims 42-50, 54-56, 58-68 and 70-81 under 35 USC 112, First paragraph (Enablement). The rejection of claims 42-50, 54-56, and 70-81 under 35 USC 112, First paragraph (Enablement) has been withdrawn.

#### ***35 USC § 102***

Applicant's response and cancellation of claim 43 filed on 10/26/2007 have overcome the rejection of claims 43 and 62-65 under 35 USC 102(b). The rejection of claims 43 and 62-65 under 35 USC 102(b) has been withdrawn.

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## Rejections Maintained

### *Rejection under Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 44, 45-48, 50, 56, 58, 62, 63, 64, 65, 66, 70-73, 75, and 81 are provisionally rejected under obviousness type double patenting over claims 1, 9, 12, 13, 44, 47, 48, and 54-59 of co-pending U.S. Patent Application No. 11/019,559. The basis of this rejection is set forth for claims 44, 45-48, 50, 56, 58, 62, 63, 64, 65, 66, 70-73, 75, and 81 at page 13 of the previous Office action of May 1<sup>st</sup>, 2007. In the response of 10/26/2007, Applicants indicated the filing of a terminal disclaimer upon the indication of allowable subject matter. The basis of this rejection is set forth for claims 44, 45-48, 50, 56, 58, 62, 63, 64, 65, 66, 70-73, 75, and 81 at page 13 of the previous Office action of May 1<sup>st</sup>, 2007.

**New Ground of Rejection**

***Claim Rejections - 35 USC § 112 (New Matter)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42, 61-63, 84, 89, and 90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection. The specification as originally filed does not provide adequate written description for the phrase "less than 16 weeks". It is not expressly asserted, nor does it flow naturally from the specification. The amended claims 42 and 61 represent a departure from originally filed. Although Applicant has pointed out the location for the support for the amended claims in the specification at the bottom of page 15 of the response of 10/16/07, the examiner was unable to locate such support. The specification does not specifically teach a subject less than 16 weeks pregnant having a level of free PIGF less than 150 pg/ml serum. Rather, the specification at page 38 teaches that serum specimens were obtained from participants prior to enrollment in the trial (13-21 weeks), at 26-29 weeks, at 36 weeks if still pregnant, and when hypertension or proteinuria were noted (page 38, lines 16-17).

In addition, the previous claim 42 (filed 04/27/2006) recited "at 13-16 weeks" and not the phrase "less than 16 weeks".

### **Conclusion**

Claims 42, 44-48, 50, 56, 58, 61-66, 70-73, 75, 81, 84, 89, and 90 are not allowed.

Claims 41, 49, 54-55, 59-60, 67-68, 74, 76-80, 82-83, 85-88, 91 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### **Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Patent Examiner  
Art Unit 1647  
December 19, 2007

/Bridget E Bunner/  
Primary Examiner, Art Unit 1647